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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements

AGENCY:

United States Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration

ACTION:

Notice of Public Listening Session

SUMMARY:

The Substance Abuse and Mental Health Services Administration (SAMHSA) announces that it will hold a public listening session on August 2, 2016, to solicit comments regarding the supplemental notice of proposed rulemaking, “Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements.” The session will be held in Rockville, MD, to obtain direct public input from stakeholders on the proposed reporting requirements.

DATES:

The listening session will be held on August 2, 2016, from 3:00 to 5:00 pm.

ADDRESSES:

Participation: The listening session will be held at the Substance Abuse and Mental Health Services Administration at 5600 Fishers Lane, Rockville, MD 20857, Room 5N54.

SAMHSA will post the agenda and logistical information on how to participate in person or by phone on <https://www.eventbrite.com/e/public-listening-session-mat-for-opioid-use-disorder-reporting-requirements-tickets-26685870156> in advance of the listening session.

The session is open to the public and the entire meeting’s proceedings will be recorded and made publicly available. Interested parties may participate in person or by phone. Capacity is limited and registration is required. To register, go to <https://www.eventbrite.com/e/public-listening-session-mat-for-opioid-use-disorder-reporting-requirements-tickets-26685870156>. Registration will be open until we meet maximum capacity. In addition to attending the session in person and joining via phone, the Agency offers several ways to provide comments in advance of the listening session, as enumerated below. The forum will begin with opening remarks from the SAMHSA official charged with moderating the session. The session is accessible to persons with disabilities.

You may submit comments using any of the following methods:

- Mail: The Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Room 13E21C, Rockville, MD 20857
- Hand Delivery or Courier: 5600 Fishers Lane, Room 13E21C, Rockville, MD 20857 between 9 a.m. and 5 p.m., ET, Monday through Friday, except federal holidays.
- Email: *WaiverRegulations@SAMHSA.hhs.gov*.

Each submission must include the Agency name and the docket number for this notice. Comments must be received by 5:00 p.m. ET on August 8, 2016.

FOR FURTHER INFORMATION CONTACT: For information concerning the listening session or the live webcast, please contact: Phillip Ames, Special Assistant, SAMHSA, 5600 Fishers Lane, 18E61, Rockville, MD 20857, (240) 276-2129 or email *WaiverRegulations@SAMHSA.hhs.gov*.

Background

On March 30, 2016 HHS issued a Notice of Proposed Rulemaking (NPRM) entitled “Medication Assisted Treatment for Opioid Use Disorders” in the Federal Register. On July 8, 2016, HHS published a final version of this rule with the same title. The final rule increases access to medication-assisted treatment (MAT) with certain medications, including buprenorphine and combination buprenorphine/naloxone (hereinafter referred to as buprenorphine) medications, in office-based setting as authorized under section 303(g)(2) of the Controlled Substances Act (CSA) (21 U.S.C. § 823(g)(2)). Section 303(g)(2) of the CSA allows individual practitioners to dispense or prescribe Schedule III, IV, or V controlled substances that have been approved by the Food and Drug Administration (FDA) without obtaining a separate registration to dispense narcotic maintenance and detoxification drugs under section 303(g)(1). Section 303(g)(2)(B)(iii) of the CSA also allows qualified practitioners who file an initial notification of intent (NOI) to treat a maximum of 30 patients at a time with medications covered under section 303(g)(2)(C). After 1 year, the practitioner may file a second NOI indicating his/her intent to treat up to 100 patients at a time. The final rule expands access to MAT by allowing eligible practitioners to request approval to treat up to 275 patients under section 303(g)(2) of the CSA. The final rule includes requirements to help ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted.

The March 30, 2016 NPRM included a set of reporting requirements for practitioners who were approved to treat patients at the higher patient limit. The purpose of the proposed reporting requirements was to help HHS assess practitioner compliance with the additional responsibilities of practitioners who are authorized to treat up to the higher patient limit. The proposed reporting requirements are as follows:

- a. The average monthly caseload of patients received buprenorphine-based MAT, per year

- b. Percentage of active buprenorphine patients (patients in treatment as of reporting date) that received psychosocial or case management services (either by direct provision or by referral) in the past year due to:
 - 1. Treatment initiation
 - 2. Change in clinical status
- c. Percentage of patients who had a prescription drug monitoring program query in the past month
- d. Number of patients at the end of the reporting year who:
 - 1. Have completed an appropriate course of treatment with buprenorphine in order for the patient to achieve and sustain recovery
 - 2. Are not being seen by the provider due to referral by the provider to a more or less intensive level of care
 - 3. No longer desire to continue use of buprenorphine
 - 4. Are no longer receiving buprenorphine for reasons other than 1-3.

HHS received a large number of comments on these proposed reporting requirements. Some commenters expressed concerns that these requirements were too cumbersome and would serve as a disincentive to providers who are considering increasing their patient limit, while other commenters felt that the reporting requirements were not stringent enough. Because of the large number of comments and the wide variability in their scope, HHS issued a supplemental NPRM, titled, “Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements” to solicit additional public comments about the proposed reporting requirements.

In addition to seeking general comments on the proposed reporting requirements, HHS seeks comment on the following questions:

- a. Are there different or additional elements that should be reported in order to assist HHS in ensuring compliance with the final rule?
- b. Are there ways in which some elements can be combined that will lessen the burden for reporting practitioners while maintaining the important function of collecting information that ensure compliance with the final rule?
- c. Are there other ways that HHS can collect the necessary information to ensure compliance with the final rule?
- d. Would it be less burdensome to report on the number of patients in treatment for each month of the reporting period that:
 - (i) Were provided counseling services at the same location as the practitioner, and how frequently those patients utilized the counseling services;
 - (ii) The practitioner referred for counseling services at a different location?
- e. Would it be less burdensome to report on the number of patients at the end of the reporting year who had terminated utilization of covered medications?
- f. Are there other suggested changes that would be less burdensome while maintaining the important function of collecting information that ensure compliance with the final rule?

SAMHSA will hold a public listening session to provide all interested parties the opportunity to share their views on the proposed reporting requirements and the additional questions. Members

of the public are invited to attend and view the proceedings, with space available on a first-come, first-served basis (based on registration).

DRAFT AGENDA FOR THE AUGUST 2, 2016 PUBLIC LISTENING SESSION

- Welcome and introductions
- Proposed reporting requirements
- Open comment period
- Additional questions

Summer King

Statistician

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